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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/476,643	12/31/99	TOBINICK E	TOBINICK.3.0

HM12/0620

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EXAMINER	
JARVIS,W	
ART UNIT	**PAPER NUMBER**
1614	5

DATE MAILED: 06/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/476,643	Tobinick
Examiner	**Group Art Unit**
William R. A. Jarvis	1614

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-99 is/are pending in the application.

Of the above, claim(s) 30-99 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-29 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-29, drawn to a method for inhibiting the action of TNF for treating neurological conditions, classified in class 514, subclass 12+.

   II. Claims 30-49, drawn to a method for treating conditions of the optic nerve or retina, classified in class 514, subclass 12+.

   III. Claims 50-65, drawn to a method for treating muscular diseases, classified in class 514, subclass 12+.

   IV. Claims 66-82, 96, and 97, drawn to a method for inhibiting the action of TNF for treating neurological conditions, classified in class 514, subclass 323.

   V. Claims 83-90, 98, and 99, drawn to a method for treating conditions of the optic nerve or retina, classified in class 514, subclass 323.

   VI. Claims 91-95, drawn to a method for treating muscular diseases, classified in class 514, subclass 323.

2. The inventions are distinct, each from the other because of the following reasons: Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. Because these inventions are distinct for the reasons given above and the search required for one group is not required for the remaining groups, restriction for examination purposes as indicated is proper.

4. Applicant made an election in paper no. 3, filed on December 31, 1999 without traverse to prosecute the invention of group I, claims 1-29. Affirmation of this election must be made by applicant in replying to this Office action. Claims 30-99 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. This application contains claims 30-99 drawn to an invention nonelected without traverse in Paper No. 3. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,015,557. Although the conflicting claims are not identical, they are not patentably distinct from each other because both

inventions claim a method for inhibiting the action of TNF for treating neurological conditions with TNF antagonists - particularly etanercept and infliximab.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patents 5,656,272 or 5,962,481 (Le et al (submitted by applicant) and Levin et al respectively) alone or in view of applicant's submitted reference U.S. Patent 5,605,690 (Jacobs et al). Le teaches that anti-TNF antibodies and peptides are effective at treating neurodegenerative diseases; see particularly col. 6, lines 26-39. Levin teaches that TNF-alpha converting enzyme inhibitors are effective at treating at treating inflammatory diseases of the central nervous system; see the abstract and claims 9 and 10. Some of the claims differ in that they require soluble TNF receptors as TNF antagonists. However, Jacobs et al teach the use of various TNF receptors as TNF antagonists in the treatment of various diseases; see the abstract and the claims. Clearly, it would have been obvious to one skilled in the art to treat neurological conditions with soluble TNF receptors since TNF antagonists in general are known to be effective at treating various neurological conditions. Some of the claims differ in that they require treatment of neurological conditions not mentioned by the prior art. However, since the prior art teaches that TNF antagonists are effective at treating neurological inflammatory and neurodegenerative diseases in

general, one skilled in the art would expect that the compounds would also be effective at treating specific neurological conditions. The claimed amounts are obvious since it is within the skill of the artisan to determine the amount of drug that provides the therapeutic effect required by the patient while producing minimal adverse side effects.

It is suggested that applicant amend the continuity data of the application if this application also claims priority to issued application no. 09/275,070 (U.S. Patent 6,015,557). This may, in fact, be necessary if 09/256,388 went abandoned prior to the filing of the instant application. Applicant should also properly amend the continuity data on the first page of the specification. Furthermore, applicant should note that the declaration is deficient since it does not claim continuity to any application. It is also requested that applicant amend the abstract so that it reflects the elected invention and is shorter that 25 lines.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. A. Jarvis whose telephone number is (703) 308-4613.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

William R. A. Jarvis
Primary Examiner
Art Unit 1614
June 14, 2000